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The Government's Response

to the

ACOST REPORT

on

Medical Research and Health

The Department of Health

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A Report on Medical Research and Health

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1 INTRODUCTION

1.1. The Advisory Committee on Science and Technology (ACOST) published its report on "Medical Research and Health" on 2 February 1993. Its terms of reference were:

**to study selected medical and health advances with particular reference to how effectively such advances have been put into practice and the extent to which they have contributed to cost effective treatment and the delivery of health care*

**to suggest how the exploitation of the results of both UK and non-UK medical and health R&D programmes could be improved, including identifying ways of improving technology transfer links between the NHS, industry and the science base*

1.2 The Government welcomes the timely publication of this report. It shares with the authors of the report a recognition of the benefits that will accrue to everyone from effectively promoting and harnessing the outcomes of medical research. The issues raised by the report and many of its individual recommendations mirror the Government's own thinking as well as its current action. The Government also acknowledges too, the prominent part played by many of the members of ACOST's Medical Research and Health committee in advancing this important work.

1.3 Recent advances in medical research have opened up many new opportunities for improvements in the prevention and treatment of disease. The ACOST report reflects the growing concern about the transfer of the results of research into practical applications. This general concern about successfully exploiting the results of research is at the heart of the White Paper "Realising Our Potential: A Strategy for Science, Engineering and Technology". In the health field, this concern has been reflected in the establishment of the Department of Health's R&D programme and by the strategies of the other Health Departments.[1]

1.4 Medical and health research is the foundation on which some of Britain's most successful industries are built. The pharmaceutical - in which Britain is a world leader - and medical devices industries contribute significantly to the wealth, as well as the health, of the nation. This lead will be maintained in a competitive world partly through effective R&D strategies. Hence the special focus in this report on pharmaceutical and medical devices. The other areas singled out for particular attention were gene therapy and transplantation; surgery; and screening, diagnosis and prevention.

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[1] "Research for Health", Department of Health (1991); "Sharpening the Focus", Welsh Office (1992); "A Strategy for Research and Development in Health and Personal Social Services for Northern Ireland - A Consultative Paper", DHSS Northern Ireland (1993); "R&D Strategy for NHS In Scotland" (working title), Scottish Office Home and Health Department, (forthcoming 1993)

1.5 The National Health Service is a key partner in the development of much of this work. It is not just a consumer of the products of medical research but acts as a test bed, collaborator and midwife to the process of medical research and development. Transferring the benefits of research to improved patient care is at the heart of the Health Departments' research strategies for the NHS, as well as the wider strategy for England set out in "The Health of the Nation" White Paper.

1.6 The NHS strategy document produced by the Department of Health in 1991 set out three key elements in the process of developing an effective strategy. It emphasised:

> (i) evaluations of the quality, effectiveness and costs of methods of disease prevention and treatment, and on **research** into the delivery and content of health care. The development of an integrated approach between NHS R&D and biomedical research would be crucial; the practical implications of major research discoveries need to be anticipated at an early stage
>
> (ii) the systematic **development** within the NHS of the results of research by NHS clinicians and managers in three stages: the development of new methods of care; the experimental introduction of these new methods into services and evaluation in trials; and the establishment of their use throughout the NHS.
>
> (iii) a further part of the NHS programme would be to provide the **infrastructure** necessary to sustain R&D within the service, including service support for non-commercially funded research and an information strategy to underpin the initiative.

1.7 A new "Research for Health" document will be published by the Department of Health in June 1993.

1.8 This response gives a strategic overview of the Government's activity in the areas identified by the ACOST report and then considers each recommendation in turn.

2 A STRATEGIC OVERVIEW

(a) Role of the Health Departments

2.1 The research and development work of the Health Departments and the NHS is central to the Government's role in ensuring that the benefits of health and medical research are harnessed to the cause of better health care.

2.2 The importance of the Health Departments to medical research and health lies in the strategic direction and leadership they can provide through the NHS. They also play a key role in promoting alliances and common approaches which engage all the key players in the health and medical field. This collaboration embraces other Government-funded bodies, notably the research councils and the universities as well as other Government Departments.

2.3 In England, the potential role for the Department of Health in promoting effective R&D was spelt out in the House of Lords Select Committee report on "Priorities in Medical Research" (1988). This report led to the creation of a new post in the Department, the Director of Research and Development, to which Professor Michael Peckham was appointed in January 1991.

2.4 In Scotland, the Home and Health Department has identified, encouraged, and supported R&D which bears on health and health care for the population of Scotland. The Chief Scientist Organisation corporate plan identifies key priority areas for R&D and envisages further strengthening of the infrastructure and skills for research in Scotland. A comprehensive research and development strategy for the NHS will focus on facilitating a more research-orientated culture in Health Boards.

2.5 The NHS Wales R&D framework document "Sharpening the Focus" (1992) states the aim of supporting the development of NHS Wales as a knowledge driven, evaluation based enterprise. Its objectives include the strengthening of the scientific basis of health care programmes delivered by the NHS in Wales: supporting the systematic development and application of the results of research within the NHS; and encouraging the growth and development of research based health care industries in Wales. A Director of Research and Development for NHS Wales has been appointed and an NHS Wales Office of Research and Development created.

2.6 In Northern Ireland, the Department of Health and Social Services has just published a consultative paper on a comprehensive R&D strategy in the health and personal social services (HPSS). The purposes are to ensure that central support for R&D activity is more clearly targeted on illuminating and resolving issues of major concern for the content and delivery of the HPSS; that policy, management and professional decisions are increasingly informed by high quality research; and that health-related R&D infrastructure and research expertise in the Province is enhanced.

(b) NHS R&D Strategy: Research for Health

2.7 The NHS R&D strategy established by the Department of Health is part of a wider Departmental R&D remit which includes policy-linked research programmes, e.g. in support of "The Health of the Nation" White Paper; links with health-related Non Departmental Public Bodies (NDPBs), research councils and other funding bodies, including OST and other Departments. In the case of the Medical Research Council (MRC), this relationship is formalised by a Concordat which sets the framework for cooperation between Health Departments and the Council.

2.8 The aim of the NHS R&D strategy is to increase the effectiveness of the NHS by creating a coherent and sound basis for defining strategies in health care , operational policy and management. It operates through the NHS Management Executive and is advised on needs and priorities by the Central Research and Development Committee (CRDC). It is supported by a number of expert groups, including a Standing Group on Health Technology.

(c) Health Technology Assessment

2.9 A major expansion of health technology assessment is now being pursued as part of the NHS R&D strategy, launched in 1991. In particular, work is in hand to

- identify NHS needs and priorities for health technology assessment
- ensure that NHS needs are met through work funded by the NHS itself and by other research funders
- ensure that the findings of these assessments are available to decision makers throughout the NHS; and
- ensure that NHS practice reflects information on the safety, effectiveness and cost-effectiveness of health care procedures.

2.10 The CRDC's Standing Group on Health Technology and its expert panels are developing an inventory of procedures and techniques, indicating for each its current status (eg experimental, established, etc), the extent to which it has been evaluated, its cost, volume and impact on health and health care. The panels are also tracking new developments and advising on priorities for assessments linked to the development and controlled introduction of new technologies.

2.11 The NHS is being encouraged to increase the proportion of its own budget that is committed to R&D. Regional Health Authorities are funding health technology assessment initiatives as part of their contribution to the R&D strategy. The Department of Health, the MRC and the medical research charities also fund health technology assessments and the Department is also discussing NHS needs for R&D with the Economic and Social Research Council.

(d) Improved Information Systems

2.12 The NHS R&D strategy is supported by an R&D Information Systems Strategy. A major component of this is a five year programme to develop and expand existing mechanisms for collating and reviewing research findings and disseminating them in accessible forms to clinicians and managers. The Cochrane Centre to support overviews of trials was commissioned last year. Two new facilities are being commissioned this summer, one focusing on commissioned reviews of existing research data and the other on the systematic transfer of research based information into practice.

2.13 The R&D strategy places emphasis on the integration of R&D with management and clinical decision making in the NHS; the goal is a knowledge-based health service. Managers, clinicians and consumers are being actively involved in identifying R&D priorities and in considering how findings can be put into practice. The separation of the roles of providers and purchasers of health care brought about by the Governments's health reforms is promoting a culture in which research-based information is actively sought out and used by all parts of the service; providers are seeking this information to improve the services they offer, and purchasers are seeking it to underpin decisions about what health care to purchase for their local population.

(e) Cost Effectiveness

2.14 If patients are to benefit from cost-effective new interventions it is essential that resources are not wasted on interventions that are not cost effective. The department of Health and the NHS are working hard to ensure that information on the cost effectiveness of new and existing interventions is available to decision makers in the NHS and is used by them.

2.15 The emphasis on these issues and the practical suggestions in the ACOST report are most welcome.

2.16 Audit provides another important mechanism for ensuring that NHS practice takes account of information on the safety and effectiveness of health care procedures. The Health Departments have in recent years promoted and provided funds for a major programme of clinical audit.

(f) MRC Developments

2.17 In recognition of the importance attached to health services research, the Council has set up a new Health Services and Public Health Research Board which is, inter alia, responsible for all aspects of the management of the Councils programme of trials and for the infrastructure support provided by Trials Offices. In addition the Council is developing a Health Services Research Initiative which includes plans for the establishment of a directly-supported MRC Health Services Research Centre which would be multi-disciplinary and would focus on the development of new methodologies for health services research.

3 THE GOVERNMENT'S RESPONSE

This section sets out the Government's detailed response to the individual recommendations in the report taking account, where appropriate, of the points raised by the conclusions of the five Task Force groups.

Section A: Development

Innovation

This section of the report emphasised that successful development demands effective interaction between the science base and the health care market. It recommended (paragraph 2.6) *that the Department of Trade and Industry (DTI) in collaboration with the health departments create a specific MEDILINK programme to facilitate the exploitation of selected ideas from academic and research institutes and the NHS.*

ACOST Recommended Action: DTI to introduce a MEDILINK programme within the present LINK scheme

3.1 Technology for medical application already forms part of a number of LINK programmes targeted at promising areas of emerging technology. Most notable are the Medical Implants, Molecular Sensors, Selected Drug Delivery and Targeting, Protein Engineering, Nanotechnology and Cell Engineering programmes although several others also involve technology with potential application to medicine.

3.2 A significant proportion of support under the DTI Small Firms Merit Awards in Research and Technology (SMART) and Support for Products Under Research (SPUR) schemes also involves medical technology.

3.3 Information technology has an important role in the improvement of health care. The DTI and the Department of Health are contributors to the EC Advanced Informatics in Medicine (AIM) programme and the DTI supports research projects in health care informatics with market potential under the European EUREKA scheme.

3.4 The White Paper "Realising Our Potential: A Strategy for Science, Engineering and Technology" transfers the lead responsibility for LINK from DTI to the Office of Science and Technology (OST). It also provides for the LINK Steering Group to report jointly to the Chancellor of the Duchy of Lancaster and the President of the Board of Trade to reflect the DTI's considerable sponsorship of the scheme. Within these new arrangements, the Government will review the scope for a MEDILINK programme and take into account existing mechanisms for technology transfer and commercialisation of research products in the medical sector.

Exploitation

This section of the report highlights the importance of intellectual property for biomedical research. It recommends (paragraph 2.8) *that the Higher Education Institutions (HEIs) should, with appropriate organisations including the NHS, MRC, Association of British Pharmaceutical Industry (ABPI), Association of British Health-Care Industries (ABHI) and UK patent marketing department, design and provide training for research students and scientists in the importance of the exploitation of research and the value of intellectual property rights (IPR).*

ACOST Recommended Action: HEIs to facilitate design and provide training in the importance of IPR

3.5 The Government recognises that it is important that intellectual property generated by universities and colleges receiving public funding should be adequately protected and exploited to the benefit of the contracting parties and of the UK economy generally. Proper understanding of the value of IPR is necessary for the effective development and dissemination of innovations, and is a key means of ensuring wider benefits from the practical results of fruitful, publicly-funded research. Researchers and scientists need to be fully aware of the importance and value of IPR.

3.6 The Cabinet Office report "Intellectual Property in the Public Sector Research Base", published in September 1992, recognised that universities are showing a greater awareness of IPR and noted that the MRC has been active in protecting and exploiting the IPR generated from its research. The Committee of Vice Chancellors and Principals (CVCP) has issued guidance to the HEIs on the management of collaborative ventures with industry. The Research Councils have taken steps to satisfy themselves that HEIs to which they make grants have satisfactory exploitation arrangements in place. As part of the NHS R&D strategy, IPR relevant to NHS interests is currently under review.

3.7 The Patent Office has developed a major training package on patents and IPR, the Patent Training Package, for use in HEIs and elsewhere. In March 1993 a free training package was offered to every UK university, and by the end of April two-thirds already had them in place. One of the main conditions of the offer is that each holder of the package actively promotes it to undergraduates and to assist in this the Patent Office has produced a recommended short course which employs the pack and is specifically targeted at undergraduates. The Patent Office is monitoring the progress of the initiative.

3.8 The Government recognises the need for those concerned with research to be aware of the importance of exploitation of research and the value of IPR. However, it is for universities themselves as autonomous bodies to decide how to take this forward in collaboration with research funding bodies, in the light of their own particular needs and circumstances.

3.9 The Government welcomes this recommendation and hopes that the ACOST report will provide a further stimulus to existing developments in this field both in relation to health and more widely.

Role of Patents

The report considered the role of patents in the exploitation of science and technology. It recommended (paragraph 2.10) *that the National Patent Office and the European Patent Office initiate legislative changes to allow publication of a discovery with protection of IPR provided a patent is filed within 12 months after publication*

ACOST Recommended Action: Patent Office to allow a twelve month period of grace

3.10 The Government endorses the recognition in the report that where research results in exploitable science and technology, a patent application should be filed before publication. It accepts that a grace period would provide a useful safety net for those cases where, for whatever reason, the inventor has published the invention before filing an application.

3.11 The result of introducing a grace period would increase the time during which it is uncertain whether something described in the literature is going to be in the public domain or the subject of a patent application. For this reason, a substantial part of British industry would prefer not to have a grace period or, if there is to be one, that it should be as short as possible.

3.12 The provision of a grace period is one of the elements of a draft international treaty which will be the subject of a Diplomatic Conference which is expected to take place in 1994. This treaty would bring a number of advantages and the Government - while it is not committed to support a 12 month period - will support the provision of a grace period as part of the overall package provided by the treaty. Domestic legislation would, of course, be a matter for the DTI.

Section B: Assessment and Evaluation

Health Technology Assessment

This section of the report focused on the lack of effective assessment and evaluation which has prevented some advances being developed, and hindered the replacement of ineffective and outdated techniques or procedures. It recommended (paragraph 3.5) *that the NHS require all new medical devices or novel applications of existing devices to be developed only under controlled conditions, and linked to validated data collection and analysis systems in a way that will facilitate effective dissemination.*

ACOST Recommended Action: NHS to require all new devices or novel applications to be developed, only under controlled conditions and data collected in a timely and systematic way.

3.13 The Government welcomes the Report's recognition of the steps being taken to promote health technology assessment, most recently in the report published by the Department of Health on "Assessing the Effect of Health Technologies".

3.14 The Government is working to ensure that new devices or novel applications which raise important questions of safety, effectiveness or cost-effectiveness which are not covered by regulatory mechanisms are appropriately evaluated and do not pass into general use in health care until shown to be safe, effective and cost-effective.

3.15 The NHS R & D programme will provide information on the comparative costs and benefits of medical interventions advised by the Standing Group on Health Technologies. The report 'Assessing the Effects of Health Technologies' recommended that new health practice methods should be purchased only in the context of a formal evaluation of their effectiveness and cost effectiveness. The implementation of this proposal is under consideration by the NHS Management Executive. The abandonment of obsolete and ineffective techniques is of great importance. This is being tackled through the NHS R & D information strategy and by other means including the use of research information in clinical guidelines and purchaser/provider contracts.'

3.16 The Department of Health's medical devices evaluation programme is already providing the NHS with information on safety and efficacy of medical devices that have been evaluated. Furthermore, the Department of Health is through the work of the National Reporting and Investigation Centre (NATRIC) - is already providing the NHS with information on devices that have been the subject of adverse incident reports. In Scotland, the Chief Scientist Office is advised by a Committee on Health Assessment of Technology and also funds a wide range of projects on health technology assessment through their Health

Services Research Unit in Aberdeen.

3.17 The Essential Requirements of EC Directives will greatly support the development under controlled conditions of new medical devices including the collection of data in a systematic way.

3.18 With regard to the general requirements suggested in paragraph 3.5, bearing in mind the vast array of new technologies being presented to the NHS, it will be important to prioritise health technology assessment so that resources are used to the best effect. This is the approach being adopted by the Standing Group on Health Technologies. The goal is to see that innovation is not stifled, that limited R & D resources are deployed in the most effective way. The Government believes that the goal of ensuring that important developments are adequately evaluated will be achieved by the steps already being taken to promote and support an evaluative culture within the health service.

Surgical Procedures

The report expressed concern that the development and adoption of new surgical techniques was in many cases haphazard. It recommended (paragraph 3.8) *that the health departments establish a committee on safety and efficacy of procedures to review and register novel surgical procedures*

ACOST Recommended Action: The health departments to establish a committee on the safety and efficacy of procedures

3.19 The Government agrees with the view expressed in the report that new procedures need to be kept under review to identify when evaluations of safety, effectiveness and cost-effectiveness are needed. This approach is recommended in the joint advisory report on minimal access surgery established by the Department of Health and Scottish Office Home and Health Department.

3.20 Under the auspices of the NHS R&D Strategy, the newly formed CRDC Standing Group on Health Technology will fulfil this role. In particular, the Methodology Panel will deal with issues such as the evaluation of fast-moving technologies such as minimal access surgery. Like other CRDC Advisory Groups, the Standing Group will consult widely with the professions, the NHS, industry, the research community and users of health services.

3.21 The Department of Health and the NHS are already investing significantly in research and audit studies on outcomes of medical interventions, including new surgical procedures such as cochlear implants, lumbar disk micro surgery, and liver transplants. The Department has also identified Minimal Access Surgery as a research priority for 1993-94. discussions are taking place within the Department on possible research topics and we are seeking expert advice to develop these further. Investment in these areas will increase as the work of the Standing Group on Health Technology and other aspects of NHS R&D Strategy develop.

3.22 The Government has serious doubts about the feasibility of a committee on the safety and efficacy of procedures and does not believe that it would be a helpful addition to work already in hand.

Health Economics

The report highlighted the wider economic benefits generated by the pharmaceutical industry which was considered in detail by the Pharmaceutical Task Force. It noted the limited understanding of economic and quality of life assessments within the NHS, in particular it drew attention to the lack of standardisation in the production of health economic and quality of life data. It recommended (paragraph 3.11) *that the health department initiate a dialogue with the pharmaceutical/ health care industries with the objective of further developing and agreeing common and validated methodology for assessing the economic and quality of life data assembled to support individual products. Professional groups should then be identified within the health service who could, with appropriate training, assume responsibility for receiving, assessing and disseminating this data.*

ACOST Recommended Action: Health Departments and pharmaceutical/health care industries to develop and agree common and validated methodologies for economic assessment

3.23 The Government recognises the economic benefits generated by the UK Pharmaceutical industry. Currently, a joint Department of Health- Pharmaceutical industry working party is looking at a range of future options for collaboration. The Government acknowledges that the methodology and presentation of evaluation for individual products would be enhanced by dialogue and discussion with the pharmaceutical and health care industries. This could take account of the methods of assessing the economic and quality of life data for pharmaceutical, and other, products.

3.24 The Department of Health recently published the report "Assessing the Effects of Health Technologies" which emphasised that without reliable information about the cost effectiveness of health technologies, soundly based decisions cannot be made about the deployment of resources. The Department also supports the Centre for Health Economics in York.

3.25 Current Departmentally funded project work includes developing a guide on how to conduct economic evaluations alongside clinical trials and the development of a quality of life measure and set of variations for the health status in which it will provide a means of assessing the relative cost-effectiveness of different interventions. This latter will help health authorities as purchasers establish priorities between different health care activities.

3.26 The Methodology Advisory Panel of the CRDC Standing Group on Health Technology will be considering what further work may be needed to develop economic and other methods used in health technology assessment.

3.27 In Scotland, the Health Economics Research Unit, funded by the Chief Scientist Office, has been devising and considering methodologies concerned with economic assessments, health needs assessments, quality of life methodology and health care outcomes.

3.28 The Government is keeping a close interest on the use of such methodologies in other countries with different regulatory regimes. The requirement for agreement on methodology and the use of particular methods may not however be applicable or appropriate to the UK regime.

3.29 It welcomes the Task Force conclusion which seeks to encourage a greater exchange of personnel between academia and industry, an approach recently endorsed by the White Paper, "Realising Our Potential: A Strategy for Science, Technology and Engineering". There is already a number of schemes of this kind, notably the Teaching Company Scheme which is presently funded by DTI, SERC, MAFF,ESRC, DoE and the Northern Ireland Department of Economic Development.

3.30 The Task Force noted the lack of venture capital to support new health and medical R&D enterprises. The Government notes with interest the recent Stock Exchange proposals to amend their listing rules in a manner which would allow emerging pharmaceutical companies to obtain a listing before having a product on the market. It also welcomes the decision to set up a working party to consider the future of the Unlisted Securities Market.

3.31 More broadly, the Government through the DTI Innovation Unit is continuing to influence the investment community to encourage policies which fully appreciate the value of company research and development in general and the potential returns from high technology companies in particular.

Good Clinical Practice

The report said that the value of clinical trials in the UK was sometimes reduced by the lack of understanding of Good Clinical Practice (GCP) by some UK doctors. It recommended (paragraph 3.13) *that the NHS should coordinate, after appropriate discussions, the introduction of GCP training programmes for clinicians and scientists involved in the design, execution and reporting of clinical research studies*

ACOST Recommended Action: NHS to introduce GCP training programmes

3.32 The Government recommends that the NHS should coordinate, after appropriate consultations with the Medicines Control Agency and other professional and regulatory bodies, the introduction of Good Clinical Practice training programmes for clinicians and scientists involved in the design, execution and reporting of clinical research studies.

3.33 This initiative might be best taken forward through the recently established NHS Regional Directors of Research and Development (RDRDs).

3.34 In addition, the Department of Health and the Scottish Office Home and Health Department are considering how training might be provided to members of Local Research Ethics Committees (LRECs), with a view to improving ethical reviews of clinical research.

Section C: Implementation

Dissemination of Information

The report emphasised the need for an efficient dissemination of information about product performance to assist identify future needs. It recommended (paragraph 4.3) *that the NHS Supplies Authority and the Health Departments should take immediate steps to improve the rate at which useful information about product performance is fed back to suppliers recognising that such evaluation is very valuable both to users within the service and to competitive suppliers seeking to improve their product range*

ACOST Recommended Action: NHS Supplies Authority to improve the rate and quality of feedback to suppliers

3.35 The Department of Health's medical device evaluation programmes and NATRIC have for some years been providing feedback about product performance to manufacturers and suppliers.

3.36 The Government notes that EC Directives will require manufacturers to report device defects to the Department when it is acting as Competent Authority, through its Medical Devices Directorate. This will enable feedback to manufacturers on product performance. Moreover, as a Competent Authority, the Department will provide feedback to suppliers on clinical investigation data that is submitted for scrutiny under the Directives.

3.37 NHS Supplies Authority (NHSSA) customer services staff have regular dialogue with their NHS customers and monitor the range of products supplied taking into account quality, suitability and customer preference, and through this process, customer needs are identified and fed back to suppliers.

3.38 Regular meetings are held between the senior purchasing staff in NHS Supplies where information and experiences are shared in such areas as supplier performance and quality of products which helps to appraise performance on a continuing basis.

3.39 In addition, trials are arranged to evaluate new products following which feedback about product performance is provided to manufacturers and suppliers. Links are being established between the NHSSA and the NHS R&D programme.

3.40 In Scotland the Chief Scientist Office has located mechanisms for the evaluation of equipment and other NHS supplies within the Supplies Division of the common services Agency of the NHS in order to ensure that the results of these evaluations are coupled to purchasing activity. This area of work is currently being reappraised.

Adoption and Diffusion

The report drew attention to evidence that some clinicians continue to use certain protocols even when others have been demonstrated to be more effective in terms of outcome. It recommended (paragraph 4.6) *that the NHS, through its regional R&D directors, establish communication channels aimed at the scientist/clinician interface to ensure that validated procedures are effectively implemented and outdated techniques are supplanted. Any implementation programme must be underpinned by monitoring of adoption and uptake*

ACOST Recommended Action: NHS to establish implementation and monitoring programme

3.41 This recommendation is central to the NHS R&D strategy. A key aspect of the strategy is the opening of channels of communication between researchers and NHS staff, between diverse professional groups in the NHS and between consumers and the NHS.

3.42 The NHS R&D strategy supports close working with other Directorates in the NHS Management Executive to ensure that the output of the programme is taken up and appropriately exploited in the practical arena. This will involve the incorporation of research data into clinical guidelines and their use in practice through the use of research information in purchaser/provider contracts and the use of clinical audit and the routine measurement of outcomes.

3.43 The initiatives aimed at improving scientist/clinician communication include the creation of the Standing Group on Health Technology Assessment to review existing technologies for their efficacy and cost effectiveness. This is replicated at local level by the networks of the Regional Directors of Research and Development (RDRDs) which include the existing medical advisory machinery, and Regional Audit Committees.

3.44 RDRDs are developing mechanisms to ensure that validated procedures are effectively implemented and outdated techniques are supplanted, examples include moves to construct quality contracts which would specifically exclude outdated techniques.

3.45 In Scotland, the Chief Scientist Office is building strategies to improve the dissemination of information. Health Services Research Networks have been established to facilitate diffusion and adoption of research results at local level as well as to support new health services research activity. The new R&D strategy of the Department of Health and Social Services in Northern Ireland aims to promote the dissemination and implementation of research findings.

3.46 In addition to the dissemination of results of MRC research through professional journals, the MRC will in future be producing annually a list of MRC research results relevant to the NHS, forging effective links with the NHS Information Systems and collaborating with NHS regions to set up 'implementation' studies to evaluate the most effective approach to adopting the results of MRC research.

3.47 The Government notes that the pace and scale of technological change will make the task of monitoring the application of new technologies especially difficult.

Public Health Screening

The report stated that there is clear evidence that while some tests are of considerable value but are not properly or cost-effectively implemented. It recommended (paragraph 4.10):

(i) the NHS establishes a major initiative to ensure screening research directs national policy formulation

(ii) the NHS should also develop a mechanism for the national implementation of public screening services to ensure that cost-effective screening programmes are available to the public throughout the national health service

(iii) consideration needs to be given to how existing screening services could be more effectively integrated into a national programme

ACOST Recommended Action: NHS to use screening research to direct national policy formulation and to subsequently develop mechanisms for implementation of an integrated national strategy

3.48 The Government believes that the provision of screening services should reflect high quality research based evidence about effectiveness, acceptability and costs.

3.49 It has taken a number of steps to promote such an approach. Currently, the UK Health Departments, together with the MRC and the two major cancer research charities, are funding four studies into breast cancer screening costing £5 million over five years[2]. The results of this research will be used to inform national screening policy development. Research is also being supported in many other areas.

3.50 The Population Screening Advisory Panel of the CRDC Standing Group on Health Technology, established in May 1993 will advise on priorities for the evaluation of new and existing screening procedures and on new developments in screening of potential relevance to the NHS. The development of screening services is being measured against considerations of effectiveness, cost effectiveness and acceptability. This includes information on medical devices that have potential for screening which is made available through the Department of Health's medical devices evaluation programme.

3.51 The MRC's Health Services and Public Health Research Board has reviewed the field of public health screening and has produced a paper setting out the general principles for screening programmes and criteria for the appraisal of research proposals.

3.52 District Health Authorities purchase services including screening in the light of local needs and priorities. The Governments NHS R & D strategy is directed to ensuring that local decisions on screening are informed by high quality research based evidence on acceptability and cost effectiveness and that services are effectively and efficiently implemented. The Government recognises there is a case for national screening programmes in some areas and will continue to review the need for these on their merits.

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[2] These examine: the impact on mortality from breast cancer of starting to screen women annually from the age of 40; the effects of screening more frequently than every three years in women aged 50 or over; the effect of taking two x-ray views of each breast of women screened (rather than one of each breast as at present); and alternative methods of treating some of the very small cancers detected on screening. The trials are being coordinated by the Breast Screening Research sub-committee of the United Kingdom Co-ordinating Committee on Cancer Research (UKCCCR).

Organ Transplantation

The report noted that the effective transplantation of organs and cells over the past 40 years had been a major achievement of twentieth century medicine. It expressed concern that the full potential of this procedure was not being realised because of a shortage of organs for transplantation. It recommended (paragraph 4.13) *that the health departments enhance the number of organs available and investigate mechanisms to introduce an opt-out system similar to those operated in Belgium, France and Austria.* The Transplantation Task Force also considered the issue of gene therapy.

ACOST Recommended Action: Health departments to introduce opt-out system for organ donation

3.53 The Government has kept arrangements for organ transplantation under review. It recognises that the demand for organs exceeds supply throughout the world. The UK is no exception where there are about 4,000 people on dialysis awaiting kidneys. Over the last ten years the total number of transplants has doubled in the UK from 2,000 to 4,000 a year. The Government is committed to continue to increase the supply of organs through voluntary means.

3.54 Successive Governments have opposed an opt-out policy for three main reasons which are summarised below:

(i) the view that donation should be voluntary, freely and gladly given rather than legally presumed. This is the existing approach to organ transplantation and is embodied in the 1961 Human Tissue Act.

(ii) the lack of international evidence that compulsory schemes improve donation rates. Some countries have adopted opt-in schemes but there is no conclusive evidence of a relationship between the scheme and the numbers of organs donated.

(iii) the lack of public and professional support. There is no support for such a policy within the medical profession or amongst the public generally.

3.55 These issues are discussed more fully in Annex A of this response.

3.56 The Government has directed its efforts to increase the number of organs available by voluntary means. Recently, the Secretary of State for Health launched a £1.5 million television campaign to promote organ donation.

3.57 The Government is exploring the possibilities offered by new technology in facilitating organ donation. The Department of Health has funded a consultancy study into the feasibility of a computerised register of organ donors; the recommendations of this report are currently being studied.

3.58 A second study has been commissioned into why relatives refuse permission for doctors to remove organs from potential donors, occasionally against the wishes of the donor, resulting in about 30 per cent of available organs not being used.

3.59 The Transplantation Task Force also addressed the issue of gene therapy and underlined the need for an effective network between academia, medical charities, research councils and the NHS. Currently, extensive professional networks are being developed among interested parties which include the medical charities and Research Councils, the NHS and industry. Such networks will help strengthen the complementary nature of the work undertaken and avoid unnecessary duplication.

3.60 The Government's general approach in this field is to take advantage of existing structures and functions where they are able to support or develop advances in gene therapy. The Department of Health has established an NHS R&D genetics group to advise on the implications for the Health Service of advances in genetics including gene therapy. The Government welcomes the recognition in the report of the major step taken by the MRC in its initiative on the genetic approach to human health (GAHH).

ANNEX A: Organ Transplantation

(a) Background

1. The ACOST report recommends (paragraph 4.13) that the Health Departments should investigate possible mechanisms for an "opt-out" system of organ donation, claiming that the present system does not produce enough organs for transplantation.

2. An "opt-out" or "presumed consent" system of organ donation operates in some countries, among them France, Belgium and Austria. Under such a system doctors are legally empowered to remove any organs from a deceased person for transplantation unless that person had, when alive, registered their objection to this.

3. By contrast the UK and the USA, Germany and the Netherlands has an "opt-in" or "informed consent" system. Under this system organs may be removed from a deceased person for transplantation if that person has, when alive, recorded their permission.

4. The essential difference is that under an opt-out system there is a presumption in favour of removing organs for transplantation, whereas such a removal under an opt-in system would requires explicit consent, usually through a donor card or from relatives.

5. The countries which have introduced the opting out system were countries where no legislation existed which was equivalent to the 1961 Human Tissue Act. There was, therefore, no mechanism to deal with the situation where a patient had died and there were no relatives or next of kin to approach for permission to use the deceased's organs. in such cases the organs were lost. In the UK this situation should not arise as the Act allows the use of such organs.

(b) Development of Transplantation Programme

6. The total number of organs transplanted in the UK over the last ten years has increased from 1,090 to 2,496. This is partly due to an increase in the number of kidneys available for transplantation - risen by one third over the period - and partly because of the development of new forms of transplantation. A breakdown is set out in table 1 (overleaf). In 1986 3 lung transplants were performed; in 1991 the figure was 72, and in 1992 it was 89 (provisional). There are no accurate statistics on corneal grafts but we believe that 2,500 such transplants take place each year.

(c) Current Concerns

7. The ACOST report acknowledged that the developments in human organ transplantation has been a major achievement of the 20th century. The scope of the programme has developed considerably over the last ten years. However, growing demand has led to growing waiting lists - mainly for kidneys. Some 4,000 people are currently waiting for kidneys. It is the shortage of organs against this growing waiting list

that has prompted the report to recommend the introduction of an "opt-out" system in the belief that this would increase the number of available organs.

TABLE 1: Organ Transplants, United Kingdom, 1982-92, number

YEAR	KIDNEY	HEART	HEART/ LUNG	LIVER	TOTAL
1982	1033	36	-	21	1090
1983	1144	53	1	20	1218
1984	1443	116	10	51	1620
1985	1336	137	37	88	1598
1986	1493	176	51	127	1847
1987	1485	243	72	172	1972
1988	1575	274	101	241	2191
1989	1732	295	94	295	2416
1990	1730	329	95	359	2513
1991	1628	281	79	420	2408
1992[3]	1641	301	53	501	2496

Source: UK Transplant Support Service Authority

8. The report observed that although the technologies of transplantation are available, the full benefits to patients which can be achieved are not being realised because of a shortage of organs for transplantation. It declared that radical action was required because the current voluntary system has failed to increase the supply of organs to meet demand, notwithstanding recent improvements in numbers.

9. Currently, a signed donor card or other written statement is sufficient legal authority for a doctor to remove organs after death, but in practice doctors always consult the family of the deceased and will not remove organs if they object. About a third of suitable organs are not retrieved because of objections by relatives. Although around 30 per cent of the adult population claim to own a donor card, considerably less seem to carry them, and relatively few transplants stem directly from the presence of the card. Recent correspondence from Professor Peter Morris in the **Independent** indicated that 40 per cent of solid organ donors in the Oxford region were carrying a donor card in each of the years 1990-92.

(d) The Case against Opt-out.

10. The Government has consistently opposed opting out proposals such as that contained in the ACOST report for three main reasons. The first reason is on the philosophical grounds that donation should be voluntary, freely and gladly given rather

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[3] provisional

than legally presumed; secondly because there is no cogent evidence that such a scheme would improve donation rates; and thirdly because there is no clear support for such a policy in, the medical profession or the public generally.

11. The Report implies that an increase in the number of available organs will follow the introduction of a new opt-out system. The evidence from the other countries mentioned in the Report does not support this view. France experienced an increase in donation when opting out was introduced there some years ago, but a causal relationship has not been established; it was at a time when most countries were experiencing rising donation. Belgium also experienced an increase when they introduced opting out in 1986, but the rate of increase was not maintained, and in 1992 the rate of transplantation fell significantly there. Similarly Austria's transplantation rate fell significantly in 1992 , and the Austrians have been unable to show whether their opt-out scheme, introduced in 1982, had any effect upon donation. Table 2 compares kidney transplantation in Belgium, Austria and the UK in 1991 and 1992.

TABLE 2: Kidney Transplants in UK, Belgium and Austria, 1991-92, numbers

Year	Austria	Belgium	UK
1991	389	378	1628
1992	306	330	1641

Source: Eurotransplant and United Kingdom Transplant Support Service Authority

12. Austria and Belgium experienced a significant fall in the number of transplants in 1992 whereas in UK and the Netherlands, neither of which has opting out, transplantations rose. But comparisons with other countries are, in any case, problematical. One of the main sources of organs is road accidents; the UK has one of the lowest rates of road deaths whilst France and Austria are among the highest.

TABLE 3: Road Deaths in Selected European Countries, 1992

Country	Road deaths per million population
Austria	205
Belgium	202
France	200
UK	94
Netherlands	92

Source: Dept of Transport and Council of Europe

13. Experience of introducing opt-out schemes has not resulted in an unlimited supply of organs. On the contrary such new arrangements have not interfered with the current practice of the medical profession in consulting relatives before removing organs and respecting their wishes if they object. This is the case in Belgium and France where there is still provision for doctors to seek permission from relatives to remove organs. According to an article in the **Lancet**, French doctors say that 50 per cent of the families they approach refuse their permission, sometimes against the declared wish of the donor. In the UK, about 30 per cent of available organs are not used because relatives object, although such objection is most unusual if the donor's wish is already known to the relatives. The Department of Health is funding a study into the reasons why relatives refuse in this way.

(e) The Government's position.

14. Throughout the world demand for organs exceeds supply; in the UK there are currently about 4,000 people on dialysis is awaiting kidneys. Most would undoubtedly prefer transplants to dialysis and the Government fully supports increasing the supply of organs.

15. The Secretary of State for Health recently launched a £1.5 million television campaign to promote organ donation. Central to this campaign is the donor card which is well known and an extremely effective method of advertising. The campaign bears the message "carry your card at all times and discuss your wishes with your relatives".

16. Although the Government opposes opting out, it recognises the scope for new technology in organ donation. The Department of Health has funded a consultancy study into the feasibility of a computerised register of organ donors; the consultants' report has just been received and is being considered.

Further copies of this report can be obtained by writing to:
Research and Development Division (RD1)
Room 402A
Skipton House
80 London Road
Elephant & Castle
London
SE1 6LW

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